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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,852	09/20/2000	Guangping Gao	GNVPN.030AUSA	6419

7590 09/09/2003

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	12

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/665,852	GAO ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2002 and 10 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 9, applicant amended claim 1. Claims 1-24 are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 9, 11, 14, 15, 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (5,856,152) for reasons of record.

Applicant argues that the cells of the instant invention differ from the cells of Wilson et al. because a portion of the 5' ITR and all of the 3' ITR sequences are clearly excluded from the instant cells and do not contain additional adenovirus sequences, as may be present in '152.

Applicant's arguments and a review of the reference have been fully considered, but are found unpersuasive. Claim 1 (a) requires that the transgene be "under the control of regulatory sequences directing the expression thereof and flanked by AAV inverted terminal repeats". The claim does not convey exclusion of any portion of the AAV ITRs. In addition, additional adenovirus sequences are also not required by Wilson et al. since the sequences only *may* be present. Therefore, it is concluded that Wilson et al. anticipates claims 1, 2, 9, 11, 14, 15, 21-24.

Applicant also mentions that the instant invention requires no purification steps to remove helper viruses. However, Wilson et al. also anticipate this advantage, because a helper virus is only optional, see claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. as applied to claims 1, 2, 9, 11, 14, 15, 21-24 above, and further in view of Alkhatib et al. (Journal of Virology. 1988; 62 (8): 2718-27, abstract only) and Fields et al. for reasons of record.

Claims 3-8 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al., Alkhatib et al., and Fields et al. as applied to claims 1, 2, 9, 10-15, 21-24 above for reasons of record.

Applicant argues that the cited art teaches away from the instant invention of avoiding the use of a helper virus. Specifically, applicant argues that neither Alkhatib et al. nor Fields teach or suggest a method of propagating an AAV vector in the absence of helper virus. Applicant also argues that Alkhatib et al. is non-analogous to the instant invention and does not teach or suggest a cell containing only the minimal E1a, E1b and E2a gene products to produce rAAV in the absence of a helper virus.

Applicant's arguments and a review of the references have been fully considered, but are found unpersuasive. Neither Alkhatib et al. nor Fields et al. are required to teach the absence of a helper virus because this limitation is anticipated by Wilson et al. These references are

required to teach elements not taught by Wilson et al. These elements include the instant vectors or replacements.

Alkhatib et al. is analogous art because the reference teaches limitations not taught by Wilson et al. Alkhatib et al. teach replacing adenovirus E1a and E1b with a transgene to obtain high titers of stable virus in the absence of a helper virus. Alkhatib et al. also provide further motivation to express E1a and E1b from a separate vector to produce recombinant viruses in a cell line other than 293. Further, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation in producing the claimed invention because Alkhatib et al. teaches that replacing E1a-E1b is useful for producing hybrid adenoviruses and Wilson et al. uses hybrid adenovirus/AAV viruses for transgene expression in cells.

Fields et al. teaches that E2a is necessary for DNA-binding protein necessary for adenovirus DNA synthesis as well as stimulating AAV transcription and regulating transcripts from the nucleus to the cytoplasm, see the first full paragraph of the second column on page 2183. One of ordinary skill in the art would have been motivated to express E2a with the transgene on the same vector in order to ensure transport of the transgene of Wilson et al. to the cytoplasm and stimulate transcription of the transgene between AAV ITRs. The ordinary artisan would have had a reasonable expectation in producing the claimed invention because Wilson et al. also teaches E2a is required for expression of adenovirus genes, see column 10, lines 37-39.

Therefore, the combination of references teach all of the limitations claims and provide at least one motivation for combining the teachings with a reasonable expectation of success.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley

JAMES HOUSEL 9/8/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600